First experience with DCB for treatment of dialysis access stenosis
The Greek experience

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Background
Vessel Restenosis

Endovascular treatment options → Restenosis

• Coronary angioplasty: ~ 10% @ 9 months
• Carotid angioplasty: ~ 10% @ 1 year
• Iliac angioplasty: ~ 30% @ 5 years
• Femoral angioplasty: ~ 50% @ 2 years

• **AV-Fistula angioplasty:** ~ 50% @ 6 months
• **AV-Graft angioplasty:** < 50% @ 6 months

Vascular Access Restenosis

Mechanical and biochemical parameters contribute to a continuous neointimal hyperplasia formation.

Histological differences between veins and arteries

Substantial differences in blood flow dynamics (stagnation and recirculation zones)

ESRD causes marked endothelial dysfunction

- Uremia
- Oxidative stress
- Inflammation

Bessa, K.L, Ortiz, J.P. Journal of Visualization 2009
Diskin CJ, Blood Purification, 2010
Local Delivery of Paclitaxel to Inhibit Restenosis during Angioplasty of the Leg

Gunnar Tepe, M.D., Thomas Zeller, M.D., Thomas Albrecht, M.D., Stephan Heller, M.D., Uwe Schwarzwälder, M.D., Jean-Paul Beregi, M.D., Claus D. Claussen, M.D., Anja Oldenburg, M.D., Bruno Scheller, M.D., and Ulrich Speck, Ph.D.

ClinicalTrials.gov Identifier: NCT01174472

First received: July 21, 2010
Last updated: January 20, 2012
Last verified: January 2012
History of Changes
Five-years Clinical Experience with Paclitaxel-coated Balloon Angioplasty for Stenoses Causing Dysfunction of Dialysis Arteriovenous Fistula and Synthetic Grafts
Purpose

This audit was performed to evaluate the long-term safety and efficacy of paclitaxel-coated balloon (PCB) angioplasty of dysfunctional dialysis vascular access.
Flowchart

- 70 patients, 96 procedures, 105 devices
- AVF: 42 patients, 65 procedures, 73 devices
- AVG: 28 patients, 31 procedures, 32 devices
- Corrupted data: 8 patients, 8 procedures, 8 devices
- AVG: 25 patients, 28 procedures, 29 devices
- AVF: 37 patients, 60 procedures, 68 devices
- In Total: 62 patients, 88 procedures, 97 devices
General Characteristics

May 2010 – August 2014
Outcome Measures

Primary

• Target Lesion Primary Patency (TLPP) (Re-intervention-free)

Secondary

• Identification of factors influencing TLPP
• Complications rates
## Baseline Variables

**Mean Age (years)** 60 ± 14

**Gender (men/total)** 40/62 64.5%

**Cause of ESRD (#/total)**
- DM 19/62 31.6%
- GN 5/62 8%
- Unknown 26/62 41.9%
- PCKD 4/62 6.5%
- Other 8/62 12.9%

**Comorbidities (#/total)**
- DM 29/62 46.8%
- HPT 23/62 37.1%
- Smoking 22/62 35.5%
- PAD 29/62 46.8%
- Heart disease 26/62 41.9%
- Stroke 8/62 12.9%
<table>
<thead>
<tr>
<th>Type</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Native arteriovenous fistula</td>
<td>37</td>
<td>59.7%</td>
</tr>
<tr>
<td>Radio-cephalic</td>
<td>12</td>
<td>32.4%</td>
</tr>
<tr>
<td>Brachio-cephalic</td>
<td>20</td>
<td>54%</td>
</tr>
<tr>
<td>Brachio-basilic (transposed)</td>
<td>5</td>
<td>13.6%</td>
</tr>
<tr>
<td>Prosthetic arteriovenous graft</td>
<td>25</td>
<td>40.3%</td>
</tr>
<tr>
<td>Brachial</td>
<td>25</td>
<td>100%</td>
</tr>
<tr>
<td>Antebrachial</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Straight</td>
<td>24</td>
<td>96%</td>
</tr>
<tr>
<td>Loop</td>
<td>1</td>
<td>4%</td>
</tr>
</tbody>
</table>
### Procedural Baseline Variables II

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Circuit Age (years)</td>
<td>3.2 ± 2.8</td>
</tr>
<tr>
<td>De novo lesions</td>
<td>38/88 43.2%</td>
</tr>
<tr>
<td>Re-Interventions</td>
<td>50/88 56.8%</td>
</tr>
<tr>
<td>Thrombosis*</td>
<td>8/78 10.3%</td>
</tr>
</tbody>
</table>

*PCB following percutaneous declotting procedure*
# Devices

## Devices (#/total)

<table>
<thead>
<tr>
<th>Device</th>
<th>Count (#)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>INPACT</td>
<td>79/97</td>
<td>81.5%</td>
</tr>
<tr>
<td>LUTONIX</td>
<td>16/97</td>
<td>16.5%</td>
</tr>
<tr>
<td>EUROCOR</td>
<td>2/97</td>
<td>2%</td>
</tr>
</tbody>
</table>

## Size

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter (mm)</td>
<td>5.8±1.1</td>
</tr>
<tr>
<td>Length (mm)</td>
<td>67±24</td>
</tr>
</tbody>
</table>

## Post Dilation Devices*

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter (mm)</td>
<td>7±2</td>
</tr>
<tr>
<td>Length (mm)</td>
<td>66±24</td>
</tr>
</tbody>
</table>

*Dorado, Atlas, Conquest, XXXL Vascular, Armada, Passeo, Mustang, Rival*
Results
Results

AVGs

- **23 venous juxta-anastomotic lesions** (3/23 in stent graft restenosis)
- **5 axillary vein outflow lesions**
- **Mean AVG age:** 3.0 ± 1.5 y
- **Average PCB diameter:** 6.5 ± 1.0 mm (length 57.8 ± 17.5 mm)
- **Post-dilation:** 32.1% (9/28 cases)
- **Average diameter of post-dilation high pressure balloon catheters:** 8.0 ± 2.0 mm (length 68 ± 33 mm)
- **Clinical success and anatomic success:** 100%
## Results

### AVFs

- **Main body lesions:** 30 (50%)
- **Juxta-anastomotic lesions:** 24 (40%)
- **Cephalic arch lesions:** 2 (3.3%)
- **Subclavian vein outflow lesions:** 2 (3.3%).
- **Average PCB diameter:** 5.6 ± 1.2 mm (length 71 ±7.1mm)
- **Post-dilation:** 28.3% (17/60 lesions)
- **Clinical success:** 100%
- **Anatomic success:** 98.4% (one rupture at the cephalic arch with a 7 mm PCB not responding to prolonged inflation → 8mm stent graft)
TLPP

@ 6 months: 70.3%
@ 1 year: 28.6%
@ 2 years: 5.9%
AVF vs. AVG

AVG 0.64 years vs. 0.76 years AVF
HR 1.12, 95% CI: 0.66 to 1.89; \( p=0.65 \)
Independent Predictors of TLPP*

De novo Lesions

Vascular Access Age <3 years

Previous Thrombosis

Stroke

*By Multivariate Cox Regression Analysis
De novo

HR: 2.54; 95%CI: 1.42 – 4.56, p=0.002
HR: 0.38; 95%CI: 0.20-0.70, p=0.002
Thrombosis

HR: 2.67; 95%CI: 1.25 - 5.72, p=0.01
HR: 3.11; 95%CI: 1.56 - 6.18, $p=0.001$
Complications

- Major: 1.1%:
  One cephalic vein rupture managed intra-procedurally with stent graft deployment

- Minor: 11.3%
  Small hematomas not requiring further treatment and not compromising dialysis
Conclusions

- In this real-life series, Paclitaxel-coated balloon angioplasty of dysfunctional dialysis access was safe and provided very satisfactory primary patency rates.

- Treatment of de novo lesions was correlated with significantly better patency.
• Initial data are promising
• Growing experience
Ongoing large multi-center trials

- DEB-after-Cutting Balloon-PTA in Dialysis Fistula Stenosis (DEB-after-CB)
  - This study is currently recruiting participants.
  - ClinicalTrials.gov Identifier: NCT02575784
  - First received: October 12, 2015
  - Last updated: October 12, 2015
  - Last verified: October 15, 2015

- Drug-Eluting Balloon Angioplasty for the Treatment of Hem
  - This study is not yet open for participant recruitment.
  - ClinicalTrials.gov Identifier: NCT01001676
  - First received: October 26, 2009
  - Last updated: November 14, 2011
  - Last verified: January 2012

- Drug Eluting Balloon for Prevention of Hemodialysis Access Restenosis (DEB)
  - This study is not yet open for participant recruitment.
  - ClinicalTrials.gov Identifier: NCT01028406
  - First received: August 21, 2013
  - Last updated: NA
  - Last verified: July 2013

- Restenosis Following
  - This study has been completed.
  - Sponsor: University Health Network, Toronto
  - Information provided by (Responsible Party): University Health Network, Toronto
First experience with DCB for treatment of dialysis access stenosis
The Greek experience